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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,316	12/11/2000	Yasuhiko Shimizu	55475(968)	7005

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12/04/2002

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EXAMINER

BOYD, JENNIFER A

ART UNIT

PAPER NUMBER

1771

7

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,316

Examiner

Jennifer A Boyd

Applicant(s)

SHIMIZU, YASUHIKO

Art Unit

1771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 4, 6 and 11-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 5 and 7-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Pre-Amendment A has been entered on December 11, 2000 as Paper No. 4.

Election/Restrictions

2. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that the search for multiple groups should be substantially overlapping. This is not found persuasive because the invention of Group I does not imply the use of a freeze-drying or air-drying manufacturing method. Therefore, the Examiner would be required to search for the article claims of Group I and, under a separate classification, the procedures of freeze-drying or air-drying during the manufacturing of collagen materials.

The requirement is still deemed proper and is therefore made FINAL.

Claim Objections

3. Claims 1 and 9 are objected to because of the following informalities: In claim 1, on line 5, the word "fiber" is misspelled. A period is missing from the end of the sentence. In claim 9, line 2, the word "collagen" is misspelled. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1771

5. Claims 1 – 3, 5, 7, 8, 9 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Claim 1 recites on lines 2 and 3 “a collagen material which is filled or had inside a substance having biocompatibility that can be degraded and absorbed in the body into a matrix of non-woven fabric-like multi-element structure of collagen fibers”. The Examiner is unsure how to interpret the phrase. Is the collagen material absorbed into a matrix of collagen fibers? Is the collagen material made of the collagen fibers? Is the collagen material the substance having biocompatibility?

7. Claim 1 recites on lines 3 and 4 that the non-woven is “fabric-like”. How does it resemble a fabric?

8. In claim 1, lines 5, 6, 7, 9 and 10, it is unclear what is meant by “composed of that in which”. The Examiner will interpret the phrase to mean “composed of”.

9. Claim 1 recites on line 5 that the collagen fibers are “plate-like”. Are they flat in shape thus resembling a plate?

10. Claim 1 recites on line 7 that the fibers overlap in the “coaxial direction”. What direction is the coaxial direction?

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1771

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 1 – 3, 5 and 7 – 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Yasuhiko (WO 98/22157).

As to claims 1 and 8, Yasuhiko teaches a collagen material made of ultra-fine fibers having a diameter of about 5 nm. The ultra-fine fibers form microfibers having diameters of about 50 nm. The microfibers form fine fibers of about 2 μm diameter. The fine fibers are laid alternately as warp and weft threads to form fiber of a diameter of about 6 μm , which are laid on each other in a coaxial direction to form disc-shaped fibers of 20 – 50 μm in diameter. The disc-shaped fibers form the ultra-fine fibrous nonwoven collagen fabric multi-layered structure. On the outside of the structure are non-fibrillated collagen layers wherein collagen molecules are dispersed as monomers. (page 5, “Optimal form for implementing the invention”).

As to claims 2 and 7, Yasuhiko teaches that the substance is formed by a freezing and freeze-drying procedure to a hydrochloric acid solution extracted from collagen (page 7, 2nd paragraph).

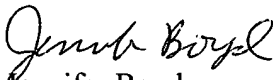
As to claims 3 and 5, Yasuhiko teaches that the substance can be a sheet of mesh-like material containing degradable and absorbable materials such as copolymers of polyglycolic acid and lactic acid (page 11, 3rd paragraph).


As to claims 9 and 10, Yasuhiko teaches, in the dry state, the collagen material has a one-point support tensile force of at least 23 N and a rupture resistance tension of at least 170 N. In the wet state, the collagen material has a one-point support tensile force of at least 2 N and a rupture resistance tension of at least 12 N.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 703-305-7082. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Jennifer Boyd
November 26, 2002


TERREL MORRIS
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